



OKLAHOMA WESLEYAN UNIVERSITY

APPLICATIONS PROCEDURES BY REVIEW TYPE

EXEMPTED REVIEW

There are several cases that may “exempt” your protocol from full IRB review. If you request an exemption, you need to submit ONE copy of the application, the research protocol, and consent form. On the application form, select one of the categories below. The following categories are exempt from full review:

Exemption Category Description	Conditions/Allowances/Limitations
1. Research, conducted in established or commonly accepted educational settings;	Not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording);	Recorded information cannot readily identify the subject or any disclosure of responses outside of the research would not reasonably place subject at risk. No children.
3. Research involving benign behavioral interventions (BBI) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection;	Recorded information cannot readily identify the subject or any disclosure of responses outside of the research would not reasonably place subject at risk. May not include medical interventions. Subject prospectively agrees. BBI must be: <ul style="list-style-type: none"> • Brief in duration • Painless/harmless • Not physically invasive • Not likely to have a significant adverse lasting impact on subjects • Unlikely that subjects will find interventions offensive or embarrassing There can be no deception unless participant prospectively agrees. No children.
4. Secondary research for which consent is not required: use of identifiable information or identifiable biospecimen that have been or will be collected for some other ‘primary’ or ‘initial’ activity;	<ul style="list-style-type: none"> • Information is publicly available; or • Information is recorded so subject cannot readily be identified and investigator does not contact subjects and will not re-identify the subjects; or



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	<ul style="list-style-type: none"> • Collection and analysis involving investigators use of identifiable health information when use is regulated by HIPAA; or • Research information is collected by or on behalf of federal government using government generated or collected information obtained for non-research activities.
5. Research and demonstration projects supported by a Federal Agency/Dept. and designed to study, public benefit or service programs;	Must be posted on a federal web site.
6. Taste and food quality evaluation and consumer acceptance studies;	
7. Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required;	All requirements for broad consent are met.
8. Secondary research involving use of identifiable private information or identifiable biospecimens for which broad consent was required.	Privacy and confidentiality protections are adequate; broad consent was obtained; documented or documentation waived; and no plan to return research results.

LIMITED EXEMPTED REVIEW

The IRB will use the expedited review procedure to review research for which limited IRB review is a condition of exemption. If you request a limited exempt review, you need to submit ONE copy of the application, the research protocol, and consent form. On the application form, select one of the categories below. The IRB conducts a limited review of privacy and confidentiality for all the following exempt categories with the stated limitations:

Limited Exemption Category Description	Limitations
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording);	Information is recorded with identifiers.
3. Research involving benign behavioral interventions (BBI) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.	Information is recorded with identifiers.



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Table with 2 columns and 2 rows. Row 1: 7. Storage or maintenance of identifiable private information... There is a change made for research purposes... Row 2: 8. Secondary research involving use of identifiable private information...

EXPEDITED REVIEW

Expedited review is provided for research that involves no more than minimal risk or for review of minor changes in previously approved research protocols. In order to approve research covered by the regulations, an IRB subcommittee will determine that all of the following requirements are satisfied. (The list below is utilized for all projects under IRB review):

- risks to subjects are minimized;
risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result;
selection of subjects is equitable;
informed consent will be sought from each prospective subject or the subject's legally authorized representative;
informed consent will be appropriately documented;
when appropriate, the research plan makes adequate provision for monitoring data collected to ensure safety of subjects; and
when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Submit ONE copy of the application, the research protocol, and consent form. On the application form, select one of the categories below. The list includes research with human subjects that involves:

- Collection of hair and nail clippings in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
Collection of excreta and external secretions.
Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice.
Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
Collection of both supra-and subgingival plaque and calculus provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
Voice recording made for research purposes, such as investigation of speech defects.
Moderate exercise by healthy volunteers.
Study of existing data, documents, records, pathological specimens or diagnostic specimens.



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FULL REVIEW

Full committee review is required for all research involving greater than minimal risk to subjects. In addition, full review is required for all research activities involving vulnerable subject populations, including fetuses, pregnant women, human in vitro fertilization, prisoners, children, elderly, and psychiatric patients.

Submit ONE application, copy of the research protocol, consent form, and abstract of your research proposal.